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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,391	06/25/2001	Jacoba Adriana De Ronde	1930-A-PCT	9219

7590 12/17/2003

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EXAMINER

HELMER, GEORGIA L

ART UNIT PAPER NUMBER

1638

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,391

Applicant(s)

DE RONDE ET AL.

Examiner

Georgia L. Helmer

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

REQUEST FOR CONTINUED EXAMINATION

1. Applicant's request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 September 2003 has been entered.

Status of the Claims

2. Applicant has cancelled claims 21 and 22, and amended claims 1-20. Claims 1-20 are pending, and are examined in the instant action.
3. All rejections not addressed below have been withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

PRIORITY

5. The Office acknowledges the receipt, on 9 June 2003, of a certified copy of ZA 98/9427, filed 15 October 1998, the priority document for the PCT/IB99/01676, of which the instant case, US09/807391, is the national phase document. The effective filing date of the instant case is 15 October 1998.

Specification

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6. Applicant is required to update the status (pending, allowed, etc.) of all relevant parent priority applications in the first line of the specification. The status of all citations of US filed applications in the specification should also be updated where appropriate.
7. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112, second paragraph

8. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, what does “genetically modifying” mean? Does this mean incorporating heterologous DNA? Or transforming? Or making transgenic?

- “the plant seed” (line 4) lacks antecedent basis. Applicant’s starting material is a “germinating plant seed”, Examiner suggests changing all subsequent recitations of this language to recite “a germinating plant seed” .

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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10. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)). The enablement issues are: “a surfactant/wetting agent” and “vacuum infiltration”.

The nature of the invention. Applicant’s invention is a method of obtaining genetically modified plant seed including contacting germinating plant seed with a wetting agent or surfactant, contacting the wetted plant seed with an Agrobacterium comprising a DNA of interest, and subjected to vacuum infiltration, thereby genetically modifying the plant seed.

The breadth of the claims. The claims are drawn broadly to a method of genetically modifying seeds of any plant, by contacting with any surfactant or wetting agent, using vacuum infiltration or not, and then contacting with Agrobacterium having any DNA of interest.

Re: The surfactant or wetting agent:

Applicant claims a method of genetically modifying plant seeds using any surfactant. Applicant teaches a method of modification using a specific surfactant, polyether polymethyl siloxane copolymer, sold in the trade as “Break-Thru”. Surfactants are chemical agents able to decrease the surface tension of a liquid in which they are dissolved. Many surfactants are known, having many different chemistries, which

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include secondary alcohol ethoxylates, alkyl polyglucosides, alcohol alkoxyates, polyether sulfates and polyether-polymethylsiloxane-copolymers (see Dow Surfactants Products sheet, attached). Surfactants are known to be toxic to animals, plants, and bacteria, and evidenced by the product information supplied with the product label, (see attached Break-thru label). Therefore dosages and concentrations are critical in usage. It is unpredictable which specific surfactant, out of the many available, and at which dosage, will function as desired in the claimed invention. Without guidance from Applicant, one skilled in the art would need to do a myriad of experiments using different surfactants, dosages and various ratios of surfactant:Agrobacterium to find conditions which would function in the desired manner. Without further guidance, this would require excessive experimentation and impose undue burden on one skilled in the art.

Re vacuum infiltration:

Applicant claims a method using surfactant without vacuum infiltration. Applicant teaches a method using vacuum infiltration at a specific step in the process, at a specific pressure, and for a specific time. Applicant does not teach what is special about these conditions which allow them to function as desired. Vacuum treatment decreases the pressure of the system treated, pulling air and water out of biological cells and tissues, potentially disrupting membranes and rupturing cell structures. While one skilled in the art can readily apply vacuum conditions to a given system, it is unpredictable at what step in the process, at what pressure and for what duration, the process would function as desired. Finding appropriate conditions would require many

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experiments and a multiplicity of conditions, which, without further guidance, would require excessive experimentation and impose undue burden.

Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

In view of the breadth of the claims (a method of genetically modifying any plant, any surfactant or wetting agent, any *Agrobacterium*, and any conditions of vacuum treatment), the nature of the invention, the unpredictability of the art, the lack the lack of guidance in the specification, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

Even if Applicant were enabled, this would be enabled only to the extent of claims limited to germinating soybean seed according the method of Example 1, pages 5, lines 25 to page 6, line 25 of the specification.

Claim Rejections - 35 USC § 102

11. Claims 1 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Bennett, US 5,658,773, issued 19 August 1997.

Bennett teaches a method transformation using *Agrobacterium* (col 8, lines 47-65), use of a wetting agent and a seed (col 14, line 57) and legumes (col 9, lines 43-46).

Accordingly Bennett anticipates the claimed invention..

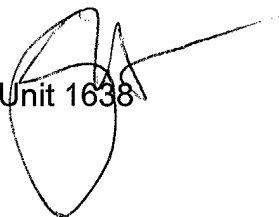
Remarks

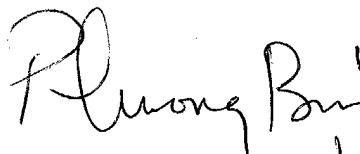
12. No claim is allowed.
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00. *Note That Examiner's phone number will change to 571-272-0796 as of 6 January 2004.*

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia Helmer PhD
Patent Examiner, Art Unit 1638
December 14, 2003




PHUONG T. BUI
PRIMARY EXAMINER
12/15/03